REMARKS/ARGUMENTS

Petition is hereby made under the provisions of 37 CFR 1.136(a) for an extension of three months of the period for response to the Office Action. The prescribed fee is enclosed.

It is noted that SEQ ID Nos: 1 to 16 are examined in this application.

The Examiner rejected claims 10, 11, 14 and 16 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In this regard, the Examiner considered the phrase "encodes a 76 kDa protein having a molecular size of about 35 kDa" in claim 10 to be vague and indefinite. It is submitted that no indefiniteness arises. As fully explained in the specification, commencing at page 9, line 23, the term "76 kDa protein" is a term used in the art to identify a certain protein of *Chlamydia*. However, research has determined that the encoding nucleotide sequence for this protein (Figure 1) in fact encodes two open reading frames, one encoding a protein of approximately 35 kDa in length (SEQ ID No: 7) and the other encoding a protein of approximately 60 kDa in length (SEQ ID No: 9).

Accordingly, it is submitted that it is entirely proper and not indefinite to refer to a 76 kDa protein having a molecular size of about 35 kDa, as specified in claim 10. A similar observation applies with respect to the phrase "encodes a 76 kDa protein having a molecular size of about 60 kDa" as specified in claim 11.

Claims 14 and 16 have been amended to refer to the respective plasmids.

Having regard to the above and the amended claims, it is submitted that claims 10, 11, 14 and 16 can no longer be considered indefinite and hence the rejection thereof under 35 USC 112, second paragraph, should be withdrawn.

The Examiner rejected claims 1, 2, 4 to 7, 9 to 17, 19 and 20 under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art.

The Examiner notes that the specification only discloses nucleotide sequence encoding MOMP (SEQ ID No: 11) or 76 kDa protein (SEQ ID No: 12) of a strain of *C. pneumoniae* and fails to provide the nucleotide sequence encoding the MOMP or 76 kDa protein derived from various species and strains of *Chlamydia*. However, the specification is addressed to a person skilled in the art. When the sequences are available to the art, it is unnecessary for applicants to have personal possession of such sequences. That person already knows the sequences described in the literature and hence it is unnecessary to provide such sequences in order for the specification to comply with the requirements of 35 USC 112, first paragraph. The written description requirement is clearly met. Accordingly, it is submitted that the rejection of claims 1, 2, 4 to 7, 9 to 17, 19 and 20 under 35 USC 112, first paragraph, should be withdrawn.

The Examiner rejected claims 1, 2, 4 to 7 and 9 to 20 under 35 USC 112, first paragraph, on the basis that the specification, while being enabled for administration of a plasmid encoding the disclosed MOMP and a plasmid encoding the disclosed 76 kDa protein of *C. pneumoniae* prior to challenge by *C. pneumoniae* and induction of a protective immune response against sublethal *C. pneumoniae* infection in mice, does not reasonably provide enablement for an immunogenic composition comprising a vector encoding any MOMP and/or 76 kDa protein derived from any species or any strain of *Chlamydia* for protection of any host, including human, against a particular disease, such as any chlaymdial infection. The Examiner states that the specification does not enable any person skilled in the art to which it pertains, nor with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

As the Examiner correctly points out, claims 1, 2, 4 to 7 and 9 to 20 are directed to an immunogenic composition for *in vivo* administration to a host comprising a first vector comprising a nucleotide sequence encoding a MOMP of a

strain of *Chlamydia* and a second vector having a nucleotide sequence encoding a 76 kDa protein of a strain of *Chlamydia* and a pharmaceutically-acceptable carrier.

The specific vectors pCAMOMP expressing MOMP and pCA76kDa expressing a 76 kDa protein of a strain of a *C. pneumoniae* are examples of the vectors defined in claim 1 and are illustrative of the invention rather than limiting. As the Examiner observes, those specific vectors are used to provide protection against *C. pneumoniae* lung infection in mice. As the Examiner will appreciate, the mouse is the animal model of choice for chlamydial infection in humans. In this regard, it is noted that the cited Stagg reference shows that the predominant choice for studies made using MOMP is mice, as summarized in Table 2 of the reference.

The Examiner states in the Office Action that:

> "The claims read on gene therapy *in vivo* because of the *in vivo* administration to a host of the immunogenic composition....."

However, this is not the case. There are no claims currently pending which are directed to a method of immunization. These claims (claims 20 to 23) were deleted in response to the prior Office Action. The claims pending are all directed to an immunogenic composition. It is not clear why, therefore, the Examiner considers the claims to read on gene therapy. The references cited by the Examiner in this regard, therefore, are irrelevant. In any event, the references do not refer to chlamydial infection.

The Examiner states that:

> ".... The specification also fails to provide adequate guidance and evidence for the use of the claimed immunogenic composition in protecting or treating disease or disorder other than chlamydial infection."

The specification does not claim to provide protection against other than chlamydial infections. It is unclear why the Examiner considers that the use of antigen of Chlamydia could possibly be used to prevent other infections. The specification is self-evident in this respect.

Having regard to the above, it is submitted that claims 1, 2, 4 to 7 and 9 to 20 are fully enabled and hence the infection thereof under 35 USC 112, first paragraph, in this regard, should be withdrawn.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**."

It is believed that this application is now in condition for allowance and early and favourable consideration and allowance are respectfully solicited.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 14 and 16 have been amended as follows:

14. (Amended) The immunogenic composition of claim 13 wherein said first plasmid vector is [has the identifying characteristics of] pCAMOMP as seen in Figure 4.

16. (Amended) The immunogenic composition of claim 15 wherein said second plasmid vector is [has the identifying characteristics of] pCA76kDa as seen in Figure 2.